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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,688	12/06/2004	Yoshihiro Motomiya	MOTOMIYA I	6615
1444	7590	10/26/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			DEBERRY, REGINA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/516,688

Applicant(s)

MOTOMIYA ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

The amendment filed 07 August 2006 has been entered in full. New claim 8 was added. Claims 3-5 and 8 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The rejection of claims 3 and 5 under 35 U.S.C. 102(b) as being anticipated by Abendroth *et al.* (Erythropoietin enhances histomorphometric signs of renal osteodystrophy. Bone (1997) Vol. 20, No. 4 SUPPL., pp. 83S. Abstract. Meeting Info: 25th European Symposium on Calcified Tissues. Harrogate, England, UK. April 25-29, 1997), as set forth at pages 4-5 of the previous Office Action (07 February 2006) is *withdrawn* in view of Applicant's arguments (07 August 2006).

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Abendroth *et al.* as applied to claim 3 above, and further in view of Nielsen *et al.* US 2002/0061849 A1, as set forth at pages 5-6 of the previous Office Action (07 February 2006) is *withdrawn* in view of Applicant's arguments (07 August 2006).

**Claim Rejections-35 U.S.C. § 112, First Paragraph, Enablement**

Claims 3-5 and (new claim 8) remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis for this rejection is set forth at pages 2-4 of the previous Office Action (07 February 2006),

Applicant states that the claims have been amended and now focus on renal failure-associated metabolic disease.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. The instant claims read on treating the subpopulation of renal-failure associated metabolic bone disease patients for this aspect of metabolic bone disease as well as all other forms of bone metabolic bone disease. The claims still broadly encompass treating all forms of bone metabolic bone disease. As was stated in the last Office Action, the specification and the art of record fail to teach the adenine-induced chronic renal failure rat model (animal model employed in the instant specification) as an animal model for all metabolic bone diseases. Yokozawa *et al.* (Nephron 44:230-234, 1986, reference submitted by Applicant) teach that long term feeding of adenine to rats produced metabolic abnormalities resembling chronic renal failure in humans. Yokozawa *et al.* teach that long term adenine feeding provides a model which would be useful to study chronic renal failure. The instant specification teaches that bone density of the femur of the adenine animal model was measured by a bone mineral analyzer, with attention being focused on the relationship between the renal failure in this model and a decrease in bone mineral (page 2, line 23-page 3, line 1). The specification teaches that the adenine model in which renal failure developed, was a pathological animal model showing complications such as renal osteodystrophy, which is a metabolic bone disease. Metabolic bone disease is a broad term, which encompasses many diverse diseases/conditions. There are other elements and etiologies, which characterize

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metabolic bone diseases that are vastly different. The animal model is a model for renal failure-associated metabolic bone disease but the specification is not enabling for treating all metabolic bone diseases. Amending the claim to recite **a method of treatment of renal failure-associated metabolic bone disease** comprising administering an effective amount of erythropoietin for said treatment to a patient with renal failure-associated metabolic bone disease would obviate the instant rejection.

#### **NEW CLAIM REJECTIONS**

##### **Claim Rejections-35 U.S.C. § 112, First Paragraph, Written Description (New Matter)**

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: **"renal failure-associated osteoporosis"**.

Applicant's amendment, filed 07 August 2006, does not provide sufficient direction for the written description for the above-mentioned "limitations". The Examiner has located diseases for which EPO is indicated in the instant specification. The specification states "diseases, for which EPO of the present invention is indicated, are bone diseases showing impairments in bone metabolism, including for example, renal

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failure-associated osteodystrophy, marble bone disease, diabetic neuropathy and osteoporosis (page 6, lines 17-21). The Examiner cannot locate the wording or connotation of the instant claim (renal failure-associated osteoporosis).

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claim now recites limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

### **Claim Rejections - 35 U.S.C. § 112, Second Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites, "a method of treatment of metabolic bone disease, comprising administering an effective amount of erythropoietin for said treatment to a patient with renal failure-associated metabolic bone disease". The breadth of the instant claims is not clear because the body of the claims and the preamble is not consistent.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
RMD  
10/16/06

  
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10/24/06  
A11647